

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation of the Effect of Methylene Blue with Supplements in the Treatment of Patients with Moderate to Severe Outpatient COVID-19 Infection in Comparison with the Control Group

Protocol summary

Registration timing: **prospective**

Study aim

Determining the effect of methylene blue with supplements on reducing the symptoms of hospitalization and mortality of patients with COVID virus 19 referred to the lung clinic

Design

A randomized, controlled trial, based on outpatients with COVID-19, which has two parallel groups.

Settings and conduct

COVID-19 patients with positive PCR or HRCT who refer to the lung clinic and are treated with methylene blue at standard dose / day (1mg /kg) and supplements

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Outpatients with COVID-19 virus referred to a Lung Clinic Confirmed by HRCT or PCR; SPO2 without Mask after Ten Minutes between 70-96; Age Over 18 Years Old. Exclusion Criteria: Pregnancy; Severe Liver and Heart Disease; Acute Renal Failure Associated with the Need for Dialysis; Glucose 6-Phosphate Dehydrogenase Deficiency.

Intervention groups

COVID-19 outpatients treated with standard medical therapy (supportive therapy) and methylene blue and supplements

Main outcome variables

Oxygen Pressure Saturation; Respiratory Rate; Headache; Cough; Fever; Shivery; Respiratory Distress; Chest Pain Wall; Vomiting; Diarrhea; Hospital Stay; Mortality Rate after One Month

Last update: **2022-05-28, 1401/03/07**

Update count: **0**

Registration date

2022-05-28, 1401/03/07

Registrant information

Name

davood attaran

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3833 2746

Email address

attarand@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2022-07-23, 1401/05/01

Actual recruitment start date

2022-06-22, 1401/04/01

Actual recruitment end date

2022-07-23, 1401/05/01

Trial completion date

2022-07-24, 1401/05/02

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220211053993N1**

Registration date: **2022-05-28, 1401/03/07**

Scientific title

Evaluation of the Effect of Methylene Blue with Supplements in the Treatment of Patients with Moderate to Severe Outpatient COVID-19 Infection in Comparison with the Control Group

Public title

Evaluation of the Effect of Methylene Blue in the Treatment of Outpatients with COVID-19 Referred to the Lung Clinic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Outpatients with COVID-19 virus referred to a Lung Clinic Confirmed by HRCT or PCR SPO2 without Mask after Ten Minutes between 70-96 Age Over 18 Years Old

Exclusion criteria:

Pregnancy Severe Liver and Heart Disease Acute Renal Failure Associated with the Need for Dialysis Glucose 6-Phosphate Dehydrogenase Deficiency

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **240**

Actual sample size reached: **240**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: simple randomization, randomization unit: individual, randomization tool: by using the website of randomization: <https://www.random.org/lists/> Simple randomization is done by random numbers generated by the randomization site, according to the list produced, individuals will be randomly assigned to the intervention (methylene blue) or control groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this single blind, the evaluator, who is a health care professional (nurse) and is responsible for collecting data (symptoms and hospitalization and mortality) from patients after using the drug, is not aware that each patient belongs to control group or intervention group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Mashhad University of Medical Sciences, Daneshgah Avenue

City

Mashhad

Province

Razavi Khorasan

Postal code

91388-13944

Approval date

2022-02-26, 1400/12/07

Ethics committee reference number

IR.MUMS.REC.1400.344

Health conditions studied

1

Description of health condition studied

Covid-19

ICD-10 code

U07.1

ICD-10 code description

Covid-19

Primary outcomes

1

Description

Oxygen pressure saturation

Timepoint

Interval time: the third day, the sixth day, the eleventh day, the fourteenth day after using Methylene Blue

Method of measurement

Pulse oximeter

2

Description

Respiratory Rate

Timepoint

Interval time: the third day, the sixth day, the eleventh day, the fourteenth day after using Methylene Blue

Method of measurement

Physical exam

3

Description

Headache

Timepoint

Interval time: the third day, the sixth day, the eleventh day, the fourteenth day after using Methylene Blue

Method of measurement

Physical exam

4

Description

Cough

Timepoint

Interval time: the third day, the sixth day, the eleventh day, the fourteenth day after using Methylene Blue

Method of measurement

Physical exam

5

Description

Shivery

Timepoint

Interval time: the third day, the sixth day, the eleventh day, the fourteenth day after using Methylene Blue

Method of measurement

Physical exam

6

Description

Chest pain

Timepoint

Interval time: the third day, the sixth day, the eleventh day, the fourteenth day after using Methylene Blue

Method of measurement

Physical exam

7

Description

Vomiting

Timepoint

Interval time: the third day, the sixth day, the eleventh day, the fourteenth day after using Methylene Blue

Method of measurement

Physical exam

8

Description

Diarrhea

Timepoint

Interval time: the third day, the sixth day, the eleventh day, the fourteenth day after using Methylene Blue

Method of measurement

Physical exam

9

Description

Fever

Timepoint

Interval time: the third day, the sixth day, the eleventh day, the fourteenth day after using Methylene Blue

Method of measurement

Physical exam

Secondary outcomes

1

Description

Hospital stay time

Timepoint

After 15 days

Method of measurement

Number of days

2

Description

Mortality rate

Timepoint

After 30 days

Method of measurement

Review of medical records

Intervention groups

1

Description

Intervention group: In addition to the standard treatment, Covid-19 outpatients are received orally methylene blue along with complementary materials two times per day in interval time 12 hours. The drug is used for 7 days until 14 days. Drug is prepared by Omid Rajabi pharmaceutical company. Methylene Blue (1 mg/Kg), Vitamin C, Glucose or sugar, Vitamine B1, B2, B3, Calcium Phosphate, Citrate Potassium, Carbonate Sodium, Glycine Amino Acid, Ginger, Lecithin, Ascorbyl Palmitate, Magnesium Stearate will be prepared as powder (in one sachet) and it will used orally after dissolving in water.

Category

Treatment - Drugs

2

Description

Intervention group: Patients will received just the standard treatment

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pulmonary clinic- Dr Davod Ataran-Dr Saeed Hafizi

Full name of responsible person

Dr Soroush Attaran

Street address

between 1st and 3rd Besat Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9176756697

Phone

+98 51 3882 8574

Email

attarand@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Majid Ghayour Mobarhan

Street address

Iman Reza Hospital, Daneshgah Avenue

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3882 8574

Email

GhayourM@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Davood Attaran

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Qaem Hospital, Ahmadabad Avenue

City

Mashhad

Province

Razavi Khorasan

Postal code

91871 45785

Phone

+98 51 3833 2746

Email

attarand@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Davood Attaran

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Qaem Hospital, Ahmadabad Avenue

City

Mashhad

Province

Razavi Khorasan

Postal code

91871 45785

Phone

+98 51 3833 2746

Email

attarand@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Davood Attaran

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

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Province

Razavi Khorasan

Postal code

91871 45785

Phone

+98 51 3833 2746

Email

attarand@mums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to

make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable